

REMARKS

Claims 21-44 are pending in the application. Claims 23-30 are under active prosecution. Claims 21, 22, and 31-44 are withdrawn as being drawn to non-elected inventions. Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Claims 21 and 23 have been amended to further clarify the intended subject matter of the claimed invention. Support for the amendment to claims 21 and 23 that recites that the immunogenic fragment comprises at least **25 contiguous amino acid residues** of a polypeptide consisting of the amino acid sequence of SEQ ID NO:1 and the polynucleotide encoding this same immunogenic fragment, respectively, can be found, for example, at page 28, lines 22-28. This section describes the production of antibodies in various hosts by immunization with "LRSP or with any fragment or oligopeptide thereof which has immunogenic properties." Also see page 8, lines 16-22 where a "fragment" is defined as follows:

A "fragment" is a unique portion of LRSP or the polynucleotide encoding LRSP which is identical in sequence to but shorter in length than the parent sequence. A fragment may comprise up to the entire length of the defined sequence, minus one nucleotide/amino acid residue. For example, a fragment may comprise from 5 to 1000 contiguous nucleotides or amino acid residues. A fragment used as a probe, primer, antigen, therapeutic molecule, or for other purposes, may be at least 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 100, 150, 250 or at least 500 contiguous nucleotides or amino acid residues in length.

Accordingly, these amendments to the claims contain no new matter. Entry of these amendments is respectfully requested.

Comments Regarding Restriction Requirement

Applicants affirm the election with traverse of Group II, which corresponds to claims 23-30 drawn to polynucleotides.

Applicants reiterate the request that the Examiner withdraw the Restriction Requirement at least with respect to claims 21, 22, 34, and 35 of Group I, and examine those claims together with the elected polynucleotide claims of Group II.

The rules under MPEP section 1893.03(d) require the Examiner to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice in national stage applications, such as the instant application filed under 35 U.S.C. 371. Applicants

believe unity of invention exists for claims drawn to the polypeptide sequence of SEQ ID NO:1 (*i.e.*, claims 21, 22, 34, and 35) and claims drawn to the elected polynucleotide sequence of SEQ ID NO:2 which encodes SEQ ID NO:1 (*i.e.*, claims 23-30) based on the rules concerning unity of invention under the Patent Cooperation Treaty. The Administrative Instructions Under The Patent Cooperation Treaty, Annex B, Unity of Invention, Part 2, "Examples Concerning Unity of Invention" provide the following guidelines with regard to unity of invention between a protein and the polynucleotide that encodes it:

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

As currently amended, the claims of Group II drawn to polynucleotides and the claims of Group I drawn to polypeptides do not encompass prior art, and the "objection of lack of unity" based on the reference of Jacobs et al. (WO 98/45436) no longer applies. Therefore, Applicants request that the Examiner withdraw the Restriction Requirement, at least with respect to claims 21, 22, 34, and 35 of Group I, and examine those claims together with the elected polynucleotide claims of Group II.

Rejoinder of method claims upon allowance of product claims under U.S. practice

The Examiner is reminded that claims 31-33, 38, and 39, drawn to methods of using the elected polynucleotides of Group II should be rejoined per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products. Applicants request that claims 31-33, 38, and 39 be rejoined and examined upon allowance of the claims drawn to the polynucleotides of Group II.

Objection to the Specification

The Examiner objected to the presence of references to hyperlinks and/or other forms of browser-executable code in the specification (Office Action, page 2). Applicants did not intend

to have active links in the specification, nor to incorporate the subject matter of websites by reference to such hyperlinks. Applicants have amended the specification to remove active hyperlinks and therefore respectfully request that the Examiner withdraw the objection to the specification.

Objections to the claims

Claims 23, 24, and 28 and claims 25-27 and 29-30 are objected to because of their dependence from non-elected claims 21 and 22. Claim 23 has been rewritten in independent form as requested by the Examiner; however, as mentioned above, Applicants believe that the claims drawn to the polypeptides of the invention, according to the unity of invention standard, should be examined with the elected claims drawn to the polynucleotides currently under examination. Applicants request reconsideration and believe amending the remainder of the claims at this time would be premature.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 23-30 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Office Action, page 3). The Examiner states that "[c]laim 23 and claims dependent thereto are dependent upon a claim to a different product" and should therefore "be rewritten in independent format." In addition, the Examiner alleges that "the language in claims 25 and 30 "comprising a polynucleotide sequence" and in claims 21, 22, and 29 "comprises an amino acid sequence" is indefinite as this could include a fragment of the entire sequence of SEQ ID NOS:1 or 2 or could include the entire sequence of SEQ ID NOS:1 or 2." Applicants respectfully disagree and traverse the rejection.

Although not conceding to the propriety of the rejection, in order to expedite prosecution, Applicants have rewritten claim 23 in independent form as requested by the Examiner.

For the record, Applicants state that the phrase "an amino acid sequence of SEQ ID NO:1" refers to the entire length of the sequence of SEQ ID NO:1. Similarly the phrase "a polynucleotide sequence of SEQ ID NO:2" refers to the entire length of the sequence of SEQ ID NO:2. The phrase "fragment of" has been used in the claims to explicitly specify a fragment of a

sequence when that was intended. Applicants believe the scope of the claims is clear. Therefore, withdrawal of the rejection under U.S.C. § 112, second paragraph is respectfully requested.

Rejection under 35 U.S.C. § 102

Claim 23 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jacobs et al. WO 98/45436 (Office Action, page 3). As currently amended, claim 23 recites that an immunogenic fragment comprising at least **25 contiguous amino acid residues** of the polypeptide of the amino acid sequence of SEQ ID NO:1 is encoded by an isolated polynucleotide. The reference of Jacobs et al. does not read on a claim that recites that the polypeptide is an immunogenic fragment that contains at least 25 contiguous amino acid residues that match SEQ ID NO:1, nor a polynucleotide that encodes such a fragment of SEQ ID NO:1. Therefore, the reference does not anticipate the claimed immunogenic fragments or polynucleotides encoding them, and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103

Claims 23 and 26-28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Jacobs et al each in view of Ciardelli et al. (US 5,837,816) (Office Action, page 4). This rejection is respectfully traversed for at least the following reasons.

To support an obviousness rejection under 35 U.S.C. § 103, "all the claim limitations must be taught or suggested by the prior art." M.P.E.P. § 2143.03. In addition, "the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made." M.P.E.P. § 706.02.

In the present case, the rejection of the claims under 35 U.S.C. § 103(a) is based on the allegation that the reference of Jacobs et al. discloses a polynucleotide sequence that encodes a fragment of SEQ ID NO:1. As mentioned above, the claims as currently amended are not anticipated by the reference. Since none of the references cited by the Examiner separately or in combination disclose or suggest the claimed sequences, withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

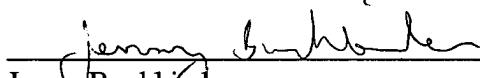
In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

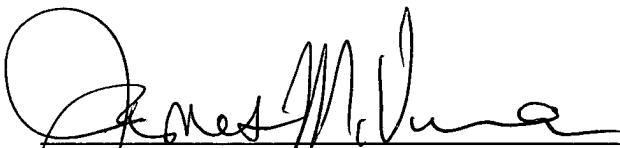
Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,
INCYTE CORPORATION

Date: October 15, 2003


Jenny Buchbinder
Reg. No. 48,588
Direct Dial Telephone: (650) 843-7212

Date: October 15, 2003


James M. Verna, Ph.D.
Reg. No. 33,287
Direct Dial Telephone: (650) 845 -5415

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886